American College of Surgeons

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December 22, 1999

Larry D. Spears
Center for Devices and Radiological Health (HFZ-340)
Food and Drug Administration
2094 Gaither Road
Rockville, MD 20850

RE: FDA's Proposed Strategy on Reuse of Single-Use Devices; Docket No. 99N-4491.

Dear Mr. Spears:

On behalf of the over 62,000 Fellows of the American College of Surgeons, I am pleased to submit the following comments regarding the Food and Drug Administration's (FDA's) "Proposed Strategy on Reuse of Single-Use Devices (SUDs)." These comments were developed in consultation with our Governors' Committee on Surgical Practice in Hospitals, and address each section of the FDA's proposed strategy.

Section I

Reconsider the agency's current policy on establishments that reprocess SUDs. The viability of reprocessed single use devices and the benefits and detriments to patient care associated with their reuse are crucial issues that must be carefully assessed. Surgeons–often unaware of the reuse status of the sterilized instruments in a surgical tray–must accept on faith that the hospital has taken the necessary precautions to prepare the operating room and its equipment for providing safe and high-quality surgical care. Thus, in reviewing the agency's proposed strategy for broader oversight of establishments that reprocess SUDs, we are pleased that FDA's primary goal in developing regulations will be "to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on good science." Indeed, we would assert strongly that any decision to restrict the use of reprocessed SUDs must be based on sound data if FDA is to produce truly credible and effective regulations.

99N-4491

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Section II

Explore the development of a device categorization system based on the level of risk presented by reprocessing and reusing SUDs and an enforcement strategy based on the level of risk. The College believes that the FDA's proposed three-tiered, risk-based categorization system ("low risk," "moderate risk," or "high risk") and the agency's proposed factors for determining an SUD's risk category are reasonable. However, we are somewhat concerned that a three-tiered system could prove to be overly complicated, so we would urge FDA to eventually assign devices to either the "high" or "low" risk categories as more scientific, device-specific data become available. This recommendation seems consistent with the agency's thinking about the "moderate risk" category as one containing many devices that are in "transition."

The final paragraph in this section discusses how, "in order to support its pre-market decisions on reusing SUDs, the agency anticipates that the reprocessor would submit valid scientific evidence showing that SUDs can be reprocessed by the methods utilized by the reprocessor for a limited or specified number of times and still be safe and effective for their intended uses." While the College agrees that adequate valid scientific data should be submitted by reprocessors, we urge the agency to accept only data that has been scrutinized through a rigorous peer-review process by clinicians familiar with use of the device.

Section III

Comments on the FDA's draft "List of Frequently Reprocessed SUDs." In reviewing the list, the College believes that most of the devices are appropriately listed, with a few exceptions. For example, we believe that orthodontic metal or plastic braces should be considered non-reuse devices except in the case of the same patient wearing the device for a considerable length of time. In addition, endotracheal tubes and non-glass syringes should not be classified as reusable devices. Finally, there should be some exception for any device that is part of a surgical tray that does not come in close proximity to the patient.

Section IV

Consider requesting original equipment manufacturers (OEMs) to provide information on their labels about risks associated with reuse of SUDs. Given the current state of knowledge, the College would hesitate to rely on OEMs to provide information on SUD labels regarding the potential risks associated with reuse of their products. Because no data have been collected on such risks by the manufacturers (or by anyone else) it seems improbable that such labels would contain any meaningful device-specific information. We also are concerned that manufacturers presently have little motivation to provide thorough and accurate information that could encourage purchasers to reprocess devices rather than purchase new ones. Finally, it is important to note that labels would be of little benefit to surgeons, who generally do not see the packaging material used for the specific instruments provided for their use in the operating room. (Packaging cannot be allowed in the sterile field.)

Section V

Examine the need to create working definitions for the terms "single-use device," "reuse," "reprocessing," and "resterilization." The College believes that the proposed definitions are adequate, but is concerned about whose standards will be used as the basis for determining such things as:

- what devices are, in fact, single use devices;
- what is the proper reprocessing method; and
- what is the gold standard for resterilization?

Will hospitals, manufacturers, or scientific literature determine these standards? Furthermore, we recommend that manufactures who request the "single-use" label be required to demonstrate through scientific studies why their product cannot be used safely again.

Section VI

Explore how recognized consensus standards can be applied to reprocessing SUDs (e.g., to verify and validate cleaning, disinfection and/or sterilization of SUDs) and explore the development of additional consensus standards to address the

safety, effectiveness, and performance of reprocessed SUDs. The College echoes observation made in the previous section, that the FDA should carefully review these consensus standards and assess their validity based on the scientific literature available. Furthermore, the agency should work with the health care community to thoroughly research this area so that truly scientific standards can be developed.

Section VII

Consider developing a research program on reuse of SUDs and explore avenues to publish and disseminate research and other information on reuse. Given the absence and critical need for data to truly ascertain what risks, if any, are posed by reuse of these devices, we are somewhat concerned that the agency listed the idea of a research program so far along in the document–almost as an afterthought. In our opinion, developing a thorough and independent research program on reuse should be the first priority in the FDA's strategy.

We are mindful of the concerns expressed by patient groups and legislators over the concept of using reprocessed single-use devices and, as surgeons who are committed to a high standard of care, we must share those concerns. However, we also believe it is imperative that regulations in this area be based on scientific evidence rather than on public apprehension or marketing considerations. Clearly, it is in the public interest for FDA, and for all of us, to learn more about the health risks associated with these products.

The College appreciates the open and carefully considered approach FDA is taking toward addressing this issue, and would be pleased to provide assistance as these efforts continue.

Sincerely,

David L. Nahrwold

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Interim Director

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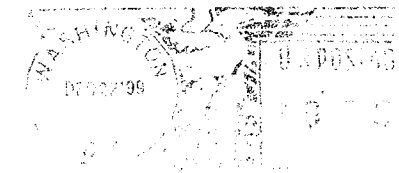

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